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10/582,915	06/14/2006	Kye-Seong Kim	0070777-000022	7421
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EXAMINER				
EPFS FORD, JANET L				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
11/26/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/582,915

Applicant(s)

KIM ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-14 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/5508)
- Paper No(s)/Mail Date 6-14-06

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group (a), claims 1-14, drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 1, the complement thereof, and sequences having 80% identity to said sequence; Applicants further elected the single nucleic acid molecule of Group (1), SEQ ID NO: 84, in the reply filed on 8/18/08 is acknowledged. The traversal is on the ground(s) that SEQ ID NO: 1-6 are members of the miR-302 gene family, and SEQ ID NO: 84-87 are precursors of the miR-302 gene family, and therefore SEQ ID NO: 1-6 and SEQ ID NO: 84-87 are related sequences and therefore should be searched together. Applicant's arguments are persuasive; therefore Groups (a)-(f) and Groups 1-4 will be searched together. However, Groups (g)-(q) (SEQ ID NO: 7-17) and Groups 5-16 (SEQ ID NO: 88-99), as defined in the restriction requirement mailed 7/16/08, are withdrawn from further consideration by the examiner, as being drawn to non-elected inventions. Thus claims 1-14 will be examined only to the extent that they read on elected inventions involving SEQ ID NO: 1-6, and SEQ ID NO: 84-87.
2. The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 7, lines 11-12; and page 9, line 5.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3 and 5-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

6. Instants claim 1 and those claims dependent therefrom, claim 2-12 encompass the following:

An isolated nucleic acid molecule, comprising

- (a) a nucleotide sequence selected from the group consisting of SEQ ID NOs: 1-17;
- (b) a nucleotide sequence which is the complement of (a);
- (c) a nucleotide sequence which has an identity of at least 80% to a sequence of (a) or (b); or
- (d) a nucleotide sequence which hybridizes under stringent conditions to a sequence of (a), (b) or (c), wherein the nucleic acid molecule was isolated from human embryonic stem cells.

Instant claim 2 recites wherein the nucleic acid molecule of claim 1 is a microRNA or (miRNA), and claim 3 further recites that the nucleic acid molecule of claim 1 is a microRNA precursor molecule.

The scope of the instant claims therefore encompass nucleic acids of any form, antisense, siRNA, dsRNA, microRNA, precursor molecule microRNA, or any other form of isolated nucleic acid comprising a nucleotide sequence that has an identity of at least

80% to SEQ ID NO: 1-17 (although only SEQ ID NO: 1-6 were searched), or has at least 80% identity to the complement of SEQ ID NO: 1-17.

The instant specification does not provide adequate description of the full scope of isolated nucleic acids having 80% identity to SEQ ID NO: 1-17 or complements thereof, encompassed by the instant claims, because neither the specification nor the prior art disclose the specific nucleotides that are essential to the claimed invention, particularly wherein the claimed isolated nucleotides are microRNAs or precursor molecule microRNAs. Without such description, the skilled artisan would not be able to envision what positions within SEQ ID NO: 1-17 can be inserted, deleted or modified to produce a variant of SEQ ID NO: 1-17 having at least 80% identity of these sequences and remains a microRNA or precursor molecule microRNA.

In order for the written description provision of 35 USC 112, first paragraph to be satisfied, applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed. For example, MPEP 2163 states in part,

"An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.").

Because the essential structural features necessary to microRNA processing elements and the nucleotide positions essential to the function of SEQ ID NO: 1-17 are unknown, the skilled artisan cannot envision the detailed structure of the encompassed isolated nucleic acid molecules.

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 13 is drawn to a method for determining the differentiation state of human stem cells, and claim 14 is drawn to a method for determining the type of stem cells, wherein said methods comprise preparing a RNA sample from the stem cells, and detecting the expression of a nucleic acid molecule having a nucleotide sequence selected from the group consisting of SEQ ID NO: 1-10 and 13-16 in the prepared RNA sample. Claims 13-14 are incomplete methods since the recited method steps do not result in the production of the objective recited in the preamble of the claims. The recited method steps result only in the detection of the expression of a nucleic acid molecule having a nucleotide sequence selected from the group consisting of SEQ ID NO: 1-10 and 13-16 in the prepared RNA sample. Claim 13 does not provide a correlating step that would result in the determination of the differentiation state of human cells, and claim 14 does not provide a correlating step that would result in determining the type of stem cell.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1-2, and 5-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Houbaviy et al. (August 2003).

Houbaviy et al. teach that the isolation, cloning, and sequencing of three libraries of miRNA sequences. In one particular aspect, Houbaviy et al. disclose the following miRNA from embryonic stem cells:

miR-302: UAAGUGCUUCCAUGUUUUGGUGA. The instant claims recite an isolated nucleic acid molecule comprising a nucleotide sequence which has an identity of at least 80% to a sequence of SEQ ID NO: 1-17 (only SEQ ID NO: 1-6, the elected invention was searched). SEQ ID NO: 1-6 have the following sequence:

miR-302b*	ACUUUAACAUGGAAGUGCUUUCU	SEQ ID NO: 1
miR-302b	UAAGUGCUUCCAUGUUUUAGUAG	SEQ ID NO: 2
miR-302c*	UUUAACAUGGGGGUACCUGCUG	SEQ ID NO: 3
miR-302c	UAAGUGCUUCCAUGUUUCAGUGG	SEQ ID NO: 4
miR-302a*	UAAACGUGGAUGUACUUGCUIIU	SEQ ID NO: 5
miR-302d	UAAGUGCUUCCAUGUUUGAGUGU	SEQ ID NO: 6

Of the sequences set forth in SEQ ID NO: 1-6 of the instant invention, SEQ ID NO: 1, 3 and 5 do not share significant sequence similarity to the prior art miR-302 sequence disclosed by Houbaviy et al. However, SEQ ID NO: 2, 4, and 6 are at least 80% identical to the prior art miR-302, see the following alignments, the nucleotides in bold are identical to the prior art sequence:

miR-302b	UAAGUGCUUCCAUGUUUUAGUAG (SEQ ID NO: 2)
miR-302:	UAAGUGCUUCCAUGUUUUUGGUGA (prior art)
miR-302b	UAAGUGCUUCCAUGUUUCAGUGG (SEQ ID NO: 4)
miR-302:	UAAGUGCUUCCAUGUUUUUGGUGA (prior art)
miR-302d	UAAGUGCUUCCAUGUUUGAGUGU (SEQ ID NO: 6)

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miR-302: **UAAGUGCUUCCAUGUUUUGGUGA** (prior art)

Claim Objections

11. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Epps-Ford
Primary Examiner
Art Unit 1633

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